

REMARKS

For the Examiner's convenience, Applicants will now address stated issues and grounds for rejection of the pending claims under the appropriate subheadings.

Amendments to the Claims

Claims 5 to 7 have been canceled. Claim 8 has been rewritten in independent format including all the limitations of Claim 2. Claims 9 and 10 have been newly added.

No new matter has been added as a result of the amendments made herein.

Rejection of Claims 5-7 Under 35 U.S.C. §103 (a)

The Examiner has rejected Claims 5 to 7 under 35 U.S.C. §103 (a) as being unpatentable over Perry *et al.* (US Patent No. 4,659,474) in view of GB 2027614 (GB '614). In particular, the Examiner stated that Perry *et al.* teach tablets coated with a with a polymer and that GB '614 teaches polydiallylamine in the free base form and salt form as a semipermeable film on a substrate. Therefore the Examiner concludes that it would have been obvious to one of ordinary skill to use polydiallylamine as the coating in the composition of Perry *et al.* to achieve the beneficial effect of a semipermeable film.

The instant claims are directed to a pharmaceutical composition comprising a unit dosage form of an effective amount of a polydiallylamine homopolymer, which is free of alkylated amine monomers and a pharmaceutically acceptable carrier. As set forth in the specification, the pharmaceutical composition can be used, for example, as a bile acid sequestrant for the treatment of hypercholesterolemia, atherosclerosis and/or reduction of serum cholesterol.

The disclosure of a tablet in Perry *et al.* does not render obvious Applicants' pharmaceutical composition in tablet form, which has a distinct structure. A tablet is defined, in one instance, in The Compact Oxford English Dictionary, Second Edition, (a copy of which is enclosed for your review, as Attachment I) as:

A small, flat, and comparatively thin piece of stone, metal, wood, ivory or other material, artificially shaped for some purpose; a small slab.

Therefore, a tablet can be a non-pharmaceutical composition such as in Perry *et al.* where the tablet is a purification and ultrafiltration membrane in tablet form. Perry *et al.* do not teach or

suggest Applicants' claimed pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer free of alkylated amine monomers and crosslinked by means of a multifunctional crosslinking agent at about 2.5-20% by weight.

Further, in the communication from the Examiner dated April 9, 2004, the Examiner states that:

In response to the applicant's argument that Perry *et al.* do not teach the polymer as an active agent, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art structure in order to patentably distinguish the claimed invention from the prior art.

However, Applicants' claimed pharmaceutical composition is structurally different from Perry *et al.* That is, Perry *et al.* teach basic polymer membrane supports (e.g., polyacrylonitrile) which can be modified by the deposition of a hydrophilic polymer (e.g., polyethyleneimine) on the membrane and then optionally crosslinked. The polymers are used in ultrafiltration and reverse osmosis processes for the concentration and purification of liquids.

Perry *et al.* mention polydiallylamine polymers at Col. 8, line 62 and tablets at Col. 12, line 25. However, the tablets described at Col. 12, line 25 of Perry *et al.* are not tablets of polydiallylamine. Rather, the tablets described at Col. 12, line 25 of Perry *et al.* are tablets of the modified filtration membrane (e.g., an acrylonitrile polymer modified by deposition of a polyethyleneimine). Further, at Col. 8, line 62, Perry *et al.* teach a long list of hydrophilic polymers, which can be used to modify the basic polymer membrane of the filtration devices described. Clearly, these teachings in Perry *et al.* taken either separately or in combination neither teach nor suggest a pharmaceutical composition comprising a unit dosage form of crosslinked polydiallylamine homopolymer which is free of alkylation and a pharmaceutically acceptable carrier.

GB '614 does not cure the deficiencies of Perry *et al.* GB '614 discloses a semipermeable composite membrane comprising a microporous substrate and a thin semipermeable film of a polymeric material deposited on one side of the substrate. The thin film can be polydiallylamine. This disclosure of polydiallylamine as a coating for a porous composite membrane in combination with Perry *et al.* (polymeric membrane supports of, for example,

polyacrylonitrile) does not make obvious Applicants' claimed pharmaceutical composition of crosslinked polydiallylamine homopolymer which is free of alkylation and a pharmaceutically acceptable carrier.

Applicants believe all pending claims meet the requirements of 35 U.S.C. §103 (a) and are patentable over the teachings of Perry *et al.* either alone or in view of GB '614. However, in order to expedite prosecution of the application, Claims 5 to 7 have been canceled.

Objection of Claim 8

The Examiner has stated that Claim 8 is objected to as being dependent upon a rejected base claim. The objection is not understood as Claim 8 is dependent on Claim 2, which the Examiner has stated is allowed. However, in an effort to expedite prosecution, Claim 8 has been rewritten in independent format including all the limitations of Claim 2, as requested by the Examiner. Clarification is requested in the next Communication from the Office.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,
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THE COMPACT OXFORD ENGLISH DICTIONARY

SECOND EDITION

COMPLETE TEXT
REPRODUCED MICROGRAPHICALLY

Attachment 1

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